

REMARKS

Claims 1-24, 33 and 34 are pending. Applicants have not amended, cancelled, or added new claims herein. In light of the following remarks, Applicants respectfully request reconsideration and allowance of all pending claims.

Withdrawal of 35 U.S.C. § 103 Rejections

Applicants thank the Examiner for the withdrawal of the rejections over Gaynor *et al.* and Perkes under 35 U.S.C. § 103(a).

Rejections under 35 U.S.C. § 103(a)

The Office rejected claims 1-24, 33 and 34 under 35 U.S.C. § 103(a) as being unpatentable over Perkes (WO 99/07400) ("Perkes") in view of Shrikhande *et al.* (U.S. Pat. No. 6,544,581) ("Shrikhande"). In particular, the Office stated that Perkes discloses dietary supplements comprising grape seed, grape skin, bilberry, and gingko biloba extracts, but does not disclose the use of Muscat grape seed extracts. The Office stated that Shrikhande teaches Muscat grape seed extracts as a source of polyphenols to incorporate into dietary supplements. Moreover, the Office stated that one of ordinary skill in the art would be motivated to use the examples of Shrikhande in order to determine good sources of polyphenols to optimize the cardiovascular health effects of the Perkes compositions, and that any ratios of grape seed extract to grape skin extract could be met through routine experimentation, absent a showing of criticality.

Applicants respectfully disagree. Proper analysis under § 103 requires consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition, and (2) whether the prior art would also have revealed that in so making, those of ordinary skill would have had a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Claim 1 recites a dietary supplement comprising a grape skin extract and a Muscat variety grape seed extract. The Perkes reference discloses three formulations containing both

grape skin extracts and grape seed extracts. Perkes discloses that flavonoids (which Perkes indicates are polyphenolics such as catechins and procyanidins) can be included in its compositions for their cardiovascular health benefits, and that useful flavonoid sources include grape skin extracts and grape seed extracts; *see* Perkes at page 2, lines 9-18; page 14, lines 31-34; and page 15, lines 25-27. As acknowledged by the Examiner, the Perkes reference, however, does not teach or suggest any composition containing a grape skin extract in combination with a Muscat variety grape seed extract, as the present claims require.

Shrikhande does not cure the deficiencies of Perkes. Shrikhande discloses, generally, a process for purifying polyphenols from whole grapes, grape pomace, and grape seeds, *e.g.*, for inclusion of purified polyphenols in nutraceuticals. At no point, however, does Shrikhande teach or suggest a dietary supplement comprising both a grape skin extract and a Muscat variety grape seed extract, or teach or suggest that one having ordinary skill in the art should modify the Perkes compositions containing a grape skin extract and grape seed extract to specifically include a Muscat grape seed extract. Shrikhande discloses nine examples in which he purifies polyphenols from grape sources. Only one example of the nine contains Muscat grape seeds as a starting material, Example 5. In fact, Applicants note that Example 5 itself uses a *mixture* of Muscat and Chardonnay grape seeds. Importantly, Shrikhande is *silent* as to the relative amounts of Muscat grape seeds to Chardonnay grape seeds in its mixture and is *silent* as to the contribution of the Muscat grape seeds as compared to the Chardonnay grape seeds with respect to the type or amount of the polyphenolics purified in Example 5. Thus, at no point did Shrikhande teach or suggest that the Muscat variety contributed in any more meaningful way to the profile of extracted polyphenolics than the Chardonnay variety.

Moreover, Shrikhande did not teach or suggest that the profile of polyphenolics extracted from the Example 5 Muscat/Chardonnay mixture was somehow superior in quality or cardiovascular effects to any other profile extracted from other grape sources. Shrikhande's other eight examples employed mixtures of red grapes, Zinfandel grapes, Rubired grapes, or red hybrid grapes (as whole grapes, pomace, or seeds). At no point did Shrikhande indicate that the Muscat/Chardonnay mixture was a superior source of polyphenolics as compared to any of the

other eight mixtures or varieties extracted. In fact, Shrikhande pointed to the use of dark whole grapes of a red hybrid variety as a particularly useful source of polyphenols (see Example 6).

Contrary to the Examiner's assertions, Applicants respectfully assert that one having ordinary skill in the art would therefore not use the examples of Shrikhande to determine the inclusion of a Muscat grape seed extract as a good source of polyphenols in order to optimize the cardiovascular health effects of the Perkes compositions. First, Applicants note that Perkes *itself* indicated that *both* grape skin and grape seed extracts were useful sources of flavonoids, which, as indicated above, include the polyphenolic compounds purified by Shrikhande. Given such a disclosure by Perkes, one having ordinary skill in the art would have simply had no motivation to include a particular variety of grape seed extract in order to "optimize" the cardiovascular benefits of the Perkes compositions, as no "optimization" was necessary - the beneficial polyphenolics were already present in the Perkes compositions by way of its general disclosure as to inclusion of grape skin and seed extracts as sources of flavonoids. Moreover, as indicated above, Shrikhande did not teach or suggest that its Muscat/Chardonnay mixture resulted in a superior amount or type of polyphenolic compound that would contribute in an "optimal" way to the resultant health benefits of a nutraceutical composition. Thus, Applicants respectfully assert that Shrikhande's mere mention of the Muscat variety, and that mere mention only in combination with the Chardonnay variety, provides no reasonable teaching or suggestion to one having ordinary skill in the art that he should modify the Perkes compositions to specifically include Muscat grape seed extracts in combination with a grape skin extract. Given all of the above, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 103(a).

Applicant : Suk Cho et al.
Serial No. : 09/800,195
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Page : 9 of 9

Attorney's Docket No.: 09143-017001

CONCLUSION

Applicants respectfully assert that all claims are in condition for allowance, which action is hereby requested. The Examiner is invited to telephone the under-signed attorney if such would expedite prosecution.

Please charge Deposit Account 06-1050 for the Petition for Extension of Time fee (one month). Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 10/26/00

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